UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

04-30182 - MAP

WESTERN DIVISION

CIVIL ACTION NO.

HISTOGENICS CORPORATION,
Plaintiff

vs.

SRS INTERNATIONAL CORPORATION,
Defendant

COMPLAINT

JURISDICTION AND PARTIES

1. The plaintiff, Histogenics Corporation (hereinafter "Histogenics") is, and at all times mentioned has been, a corporation organized and operating under the laws of the Commonwealth of Massachusetts with a place of business at 116 Pleasant Street, Easthampton, Massachusetts.

2. The defendant, SRS International Corporation (hereinafter "SRS") is a corporation with a place of business at Suite 1000, 162 K Street, NW, Washington, D.C.

3. Subject matter jurisdiction is based upon diversity of citizenship, 28 U.S.C. § 1332, the amount in controversy exceeding $75,000, exclusive of interest and costs.

4. This Court has jurisdiction over SRS International pursuant to Massachusetts General Laws Chapter 223A by virtue of the transaction of business here.

STATEMENT OF FACTS

5. Histogenics is in the business of investigating, performing research, developing, creating, licensing and ultimately marketing replacement tissue for medical implantation in the human body.

6. SRS is in the business of assisting medical science innovators in the attainment of governmental licensure for medical products, including but not limited to, the provision of regulatory and clinical guidance in the coordination, initiation and monitoring of clinical trials for governmental approval and licensure for the distribution of medical devices and materials.

7. On April 11, 2001, Laurence Tarrant and John Todhunter, the presidents of Histogenics and SRS, respectively, executed a "Master Agreement for Services". A copy of the same is appended as Exhibit A.

8. On that same day, those same individuals executed the first "Task Order". This Task Order pertained to the development, program design, coordination, management, monitoring and implementation for both non-clinical and clinical studies; regulatory and scientific strategic consultations; Federal Drug Administration regulatory affairs services, including the application and obtainment of licensure for the marketing and distribution of a tissue replacement implant system for repair of cartilage defects in, and around, the human knee. A copy of the Task Order is appended as Exhibit B.

9. After execution of both the Master Agreement and initial Task Order, SRS proposed changes, including the fees to which it would be entitled, as well as changes in the timetable for the clinical trials, presentation to governmental agencies and licensure. Histogenics agreed to some of the modifications, but did not agree to others.

10. During the period from April 11, 2001 until August 27, 2003, Histogenics paid SRS pursuant to the agreement.

11. During that period of time, SRS did not adhere to the milestones established at the inception of the agreement, or mutual modification thereof, resulting in delays in achieving clinical trials. SRS delayed in responding to Histogenics regulatory questions and gave limited attention to clinical protocol requirements. It failed to prepare support letters and gave limited attention to clinical site budget concerns and insurance issues. SRS provided limited initiative regarding assistance to clinical site coordinators as well as a limited effort regarding implementation of protocol amendments. These attentive deficiencies resulted in the need for oversight by Histogenics of the clinical and regulatory efforts and caused compounded delays in the initiation of clinical enrollment and the acquisition of regulatory licensure.

12. Therefore, on August 27, 2003, through counsel, Histogenics issued a Notice of Immediate Termination of the Master Agreement for Services with SRS. A copy of that notice is appended as Exhibit C. The Master Agreement for services expressly provides in Article Z for termination by Histogenics upon thirty (30)

days notice without cause and it is subject to immediate termination for material breach or cause. (Exhibit A).

13. As of the date of the Notice of Termination, Histogenics had paid SRS substantial sums for services under the Master Services Agreement. In addition to the performance failings of SRS, Histogenics determined that it had been overcharged in excess of $200,000 for those services actually provided by SRS, based upon the failure of SRS to achieve various performance milestones.

14. As part of the Notice of Termination, Histogenics specifically requested the immediate delivery of all work product and files pertaining to the clinical development and application for licensure of the Histogenics tissue replacement system.

15. SRS has refused and failed to provide that documentation, either in paper or electronic form. Consequently, Histogenics was compelled to engage counsel to draft a request to the Federal Drug Administration under the Freedom of Information Act for Histogenics' material with detrimental and costly delay.

16. In response to the Notice of Termination, based upon a material breach of the Agreement by SRS, SRS indicated that it had not breached the Agreement and would acquiesce in the termination only in return for the payment by Histogenics to SRS of $593,286, notwithstanding the thirty (30) day termination provision in Article Z. (Exhibit A).

17. The Master Agreement between Histogenics and SRS contains a provision for dispute resolution requiring that the parties first pursue non-binding mediation, and if no resolution is obtained, to proceed with binding arbitration. (Exhibit A).

On October 8, 2003, Histogenics, through counsel submitted a Demand for Arbitration to the Commercial Division of the American Arbitration Association and, per the advice of an administrator at the American Arbitration Association, checked off the box indicating Histogenics' willingness, in accordance with the Master Agreement, to proceed with mediation prior to binding arbitration. A copy of the Demand for Arbitration reflecting that it had been sent to SRS's counsel, John D. Pellegrin, is appended as Exhibit D.

18. On October 27, 2003, the American Arbitration Association returned to Histogenics' counsel the Demand for Arbitration/Mediation as well as the entry fee of $2,750. Inquiry at the American Arbitration Association as to the reason for the return of the submittal was made, and counsel for Histogenics was advised that because the Master Agreement did not specify the American Arbitration Association as the mediator/arbitrator and because John D. Pellegrin, counsel for SRS, had expressed an unwillingness to use the American Arbitration Association as a forum for resolution of the dispute, the submittal by Histogenics for arbitration/mediation was returned. See Exhibit E, Affidavit of L. Jeffrey Meehan.

19. On October 31, 2003, counsel for Histogenics wrote to John D. Pellegrin, counsel for SRS International, requesting that SRS agree to use the American Arbitration Association as a forum for mediation and, if necessary, binding arbitration, of the instant dispute. Neither Mr. Pellegrin nor SRS responded to this request. See Exhibits E and F.

20. On December 24, 2003 SRS filed suit against Histogenics and others in the Superior Court for the District of Columbia.

21. The suit by SRS was removed by counsel for Histogenics to United States District Court for the District of Columbia, and thereafter motions were filed for dismissal on behalf of Histogenics and the other defendants.

22. On August 16, 2004 Judge Royce C. Lamberth of the United States District Court for the District of Columbia allowed the defendants' motions to dismiss, in part because of a refusal or failure by SRS to participate in mediation and/or arbitration as provided in the agreement with Histogenics, and otherwise dismissed the complaint of SRS for lack of personal jurisdiction. Copies of Judge Lamberth's order and memorandum of decision are appended together as Exhibit G.

COUNT I

23. The plaintiff repeats and incorporates herein the allegations contained in paragraphs 1 through 22 of this Complaint.

24. SRS committed a material breach of its agreement with Histogenics to provide services for the clinical development, regulatory assistance and ultimately, licensure, for the distribution of Histogenics' products.

25. As a consequence of that breach, Histogenics has sustained substantial monetary damages associated with the delay of the licensure of its products.

COUNT II

26. Plaintiff Histogenics repeats and incorporates herein by reference the allegations contained in paragraphs 1 through 22 of this complaint.

27. Histogenics was billed for services not rendered by SRS, and as a consequence overpaid SRS in excess of $200,000.

COUNT III

28. The plaintiff Histogenics repeats and incorporates herein by reference the allegations contained in paragraphs 1 through 22 of this complaint.

29. Despite seasonable demands for the provision of all work product and files relating to the clinical development and licensure its medical devices, and the payment for the services resulting in the generation of that work product and files, SRS has refused and neglected to turn over the work product and files to Histogenics, either in paper or electronic form. As a consequence of the refusal of SRS to tender to Histogenics the latter's work product and files, Histogenics has incurred costs in attempting to obtain the information through alternative means, and has been delayed in the development and licensure of its medical devices.

COUNT IV

30. The plaintiff Histogenics repeats and incorporates herein by reference the allegations contained in paragraphs 1 through 22 of this complaint.

31. Despite repeated demands and requests to engage in mediation and, if necessary, binding arbitration for the resolution of this dispute as contemplated and provided for in the Master Agreement, SRS has refused mediation and arbitration in breach of the Agreement.

COUNT V

32. The plaintiff Histogenics repeats and incorporates herein by reference the allegations contained in paragraphs 1 through 22 of this complaint.

33. The conduct of SRS in failing to perform its obligations under the Master Agreement; in overbilling and collecting from Histogenics fees for services not rendered; for failing to adhere to the timetable established for the clinical development and application for licensure of Histogenics medical devices; for refusing, upon specific request, to tender to Histogenics its work product and files; for refusing to engage in mediation and, if necessary, binding arbitration SRS has committed unfair and deceptive acts or practices, and acted in bad faith in violation of Massachusetts General Laws Chapter 93A.

RELIEF SOUGHT

A. That this Court issue a temporary restraining order, preliminary and permanent injunctions requiring that SRS immediately tender to Histogenics all work product and files created and produced by SRS or third party vendors in the clinical development and application for licensure of Histogenics' medical devices;

B. That SRS be ordered to participate in mediation and if necessary, binding arbitration before a panel of three (3) arbitrators, under the jurisdiction of and subject to the Commercial Arbitration Rules of the American Arbitration Association at Springfield, Massachusetts and 9 U.S.C. § 4;

C. That Histogenics be awarded damages for overpayments made to SRS; for expenses and lost revenue due to the delay and failure of SRS to perform its services under the Master Agreement; and for loss of profits occasioned by that delay.

D. That Histogenics be awarded a judgment against SRS for a violation of Massachusetts General Laws Chapter 93A on the basis of its unfair and deceptive acts and practices and bad faith in its dealings with Histogenics.

E. That this Court grant such other relief as may be appropriate.

THE PLAINTIFF
HISTOGENICS CORPORATION

By _____
L. Jeffrey Meehan, Esquire
Doherty, Wallace, Pillsbury
and Murphy, P.C.
1414 Main Street, Suite 1900
Springfield, MA 01144
(413) 733-3111
(413) 734-3910 (fax)
B.B.O. Number 341440

EXHIBITS

SRS INTERNATIONAL CORPORATION

Suite 1000 • 1625 K Street, NW • Washington, DC 20006-1604
Telephone (202) 223-0157/0298 • Fax (202) 835-8970
E-Mail: mainsrs@srsinternational.com http://www.srsinternational.com

MASTER AGREEMENT FOR SERVICES BETWEEN

HISTOGENICS CORPORATION

AND

SRS INTERNATIONAL CORPORATION

Histogenics Corporation, hereafter known as CLIENT, obtains the services of SRS International Corporation hereafter known as CONSULTANT, in the fields of: FDA regulatory affairs; clinical and non-clinical sciences and study design; clinical and non-clinical research management; clinical and non-clinical data development, evaluation, and quality assurance; and, related matters. CONSULTANT agrees to provide such services in accordance with the following terms and conditions:

Article (1): Services

At times mutually agreeable to CONSULTANT and CLIENT, CONSULTANT will make available his services, commencing on the effective date of this agreement. The services provided will be as required and specified by CLIENT.

The services to be performed under this agreement will be:

(a) as detailed in Task Orders issued pursuant to this agreement (which agreement will be incorporated into said Task Orders by reference to the present "Master Agreement") and which will be for fixed fee amounts; or,

(b) may be consultations which are requested by CLIENT, verbally or in writing, but are of such a nature as to not be conveniently covered by any specific Task Order. In such case services will be provided as "hourly billed service" with the costs of such services to be billed on an hourly rate as specified in Article 3, "Compensation", of this agreement and the details of such services to be provided to CLIENT at the time of presentation of an invoice for such services. Provided, that such hourly services which are requested by CLIENT and provided to CLIENT in support of development of specific Task Orders which issue subsequent to CONSULTANT's providing these hourly services may, by mutual agreement, be credited against the fixed fee cost of the Task Order specified services.

Task Orders under this agreement are to be prepared by CONSULTANT at CLIENT's verbal or written request and will become effective when executed by CLIENT. Each such Task Order will contain a Scope of Work statement which details the services to be provided under the Task Order and provides Costs and Time Frames for completion of services under the Task Order. Time Frames for deliverables under a Task Order will be referenced to the date of approval of the Task Order by the CLIENT and other such time points as may be specified in the Task Order. Costs and Time Frames in Task Orders issued pursuant to this Agreement are predicated on the Scope of Work for each Task Order and in the event that a Scope of Work requires modification and such modification affects either Time Frame or Cost, then an Amended Task Order shall be prepared for approval by CLIENT and CONSULTANT.

Article (2): Contract Period

This Agreement becomes effective on the date of execution by CLIENT, and will continue in effect until revoked in writing by the CLIENT. The CLIENT will provide CONSULTANT 30 days written notice of intent to revoke except if such revocation is due to completion of all required tasks. The revocation of a specific Task Order shall be subject to the same 30 days notice requirement and becomes effective 30-days after written notice is provided to CONSULTANT. In the event that a specific Task Order is revoked, save for the reason of CONSULTANT's misfeasance or CONSULTANT's failure to perform under the terms of the Task Order, CLIENT agrees to pay CONSULTANT an amount which is fair and reasonable compensation for work completed since the time of the last milestone payment payable under the specific Task Order being revoked and the effective date of revocation of the specific Task Order; such "fair and reasonable compensation" to be negotiated in good faith and expeditiously between CLIENT and CONSULTANT.

Article (3): Compensation

Compensation for services under this agreement is to be provided for in Task Orders issued pursuant to this agreement.

Article (4): Terms of Payment

Terms of Payment under this agreement will be as specified in Task Orders issued pursuant to this agreement.

Any Task Order specified initiation payment, progress payment, or milestone payment invoice not paid within 10 days of receipt by CLIENT and any hourly services invoice not paid within 20 days of receipt by CLIENT shall incur a monthly finance charge at the annual rate of 18%.

Invoices for initiation payments, progress payments, or milestone payments for Task Order covered services will be presented at such times as specified in the relevant Task Order. Invoices for hourly services will normally be presented at the end of each calendar month for work in that month and shall detail the nature of work done so as to support the invoicing.

In the event that CONSULTANT is required to seek legal assistance to recover from CLIENT monies which CONSULTANT alleges are owed to CONSULTANT, CLIENT agrees to reimburse CONSULTANT for the actual costs incurred by CONSULTANT in recovering any such monies, including reasonable attorneys' fees and court costs but not including CONSULTANT's time expended by CONSULTANT's personnel in support of any such recovery action; provided, that CONSULTANT shall only be entitled to be reimbursed for its reasonable attorneys' fees and court costs if CONSULTANT obtains either a judgement against CLIENT or an arbitration award for the amount that CONSULTANT claims is due from CLIENT, and in the event of a partial award or judgement CONSULTANT shall only be entitled to recover from CLIENT a pro rata portion of its attorneys' fees and court costs.

Article (5): Independent Contractor

It is agreed that CONSULTANT shall have complete freedom as to the details, methods, and means of performing the requested services. It is further understood that CONSULTANT is retained only for the purposes and to the extent set forth in this agreement, and that CONSULTANT'S relationship to CLIENT and any of CLIENT'S subsidiary companies shall, during the period of this agreement, be that of an independent contractor. CONSULTANT'S stockholders, employees, agents, and sub-contractors shall not be considered under the provisions of this agreement or otherwise to have a status as employees of CLIENT, nor shall any such persons or parties be entitled hereafter to participate in any plans, arrangements, or distributions by CLIENT relating to any pension, deferred compensation, bonus, stock bonus, hospitalization, insurance or other benefits extended to CLIENT'S employees.

CONSULTANT shall be free to dispose of such portions of CONSULTANT'S time, energy and skill as are not obligated hereunder to CLIENT and its subsidiaries, in such manner as CONSULTANT sees fit and to such persons, firms or corporations as CONSULTANT deems advisable, so long as doing so does not create a conflict of interest between CLIENT and such other persons, firms, or corporations.

Article (6): Confidentiality

CONSULTANT shall, both during and subsequent to providing services hereunder, be bound by the terms of the Confidentiality Agreement executed between CONSULTANT and CLIENT, which Confidentiality Agreement is incorporated herein by reference.

Article (7): Prior Agreements

This agreement replaces any prior agreement(s) between CONSULTANT and CLIENT relative to services as a CONSULTANT with the exception of the Confidentiality Agreement cited in Article 6, above, which shall continue in effect. This agreement contains the entire understanding of the parties and they shall not be bound by any representations, warranties, promises, covenants or understandings other than those set forth herein.

Article (8): Indemnification

The parties hereto mutually agree to indemnify each other from claims arising against either party; provided, that CLIENT is not obligated to indemnify CONSULTANT from claims arising against CLIENT to the extent that such claims result from the negligence of, misfeasance of, or misrepresentations made by CONSULTANT and CONSULTANT is not obligated to indemnify CLIENT from claims arising against CONSULTANT to the extent that such claims result from the negligence of, misfeasance of, or misrepresentations made by CLIENT.

Article (9): Severability

In the event that any Article or Articles in this Agreement are found invalid by the court of competent jurisdiction, the remainder of this Agreement shall continue in full force and effect.

Article (10): Dispute Resolution

In the event of disputes arising under this Agreement, the parties agree to first pursue non-binding mediation and, should the dispute not be resolved after such non-binding mediation, to then enter into binding arbitration.

Approval of this Agreement

IN WITNESS WHEREOF, the said parties have hereunto set hands and seals on the day and year indicated and the signatories hereto represent and warrant that they are empowered to bind the respective parties to this agreement.

John A. Todhunter, Ph.D.
President,
SRS International Corporation

4-5-01
Date

Laurence J.B. Tarrant, Ph.D.
President,
Histogenics Corporation

4-11-01
Date

SRS INTERNATIONAL CORPORATION
Suite 1000 • 1625 K Street, NW • Washington, DC 20006-1604
Telephone (202) 223-0157/0298 • Fax (202) 835-8970
E-Mail: mainsrs@srsinternational.com http://www.srsinternational.com

TASK ORDER

NUMBER: HISTOGENICS-00-001

ISSUED TO: SRS International Corporation

ISSUED BY: Histogenics Corporation

PURSUANT TO: Master Agreement for Consulting Services

DATE: Effective on Execution by Histogenics Corporation

SCOPE OF WORK:

SRS International will develop and provide to the issuer of this Task Order the following materials, services, and/or work products:

- Regulatory and scientific strategic consultations;
- FDA regulatory affairs services;
- Data development program design, coordination, management, monitoring and implementation for non-clinical and clinical studies;
- Evaluation, analysis, and reporting of the results on non-clinical and clinical studies; and,
- GMP consultations

in support of the development of and FDA approval of Histogenics Corporation's TES tissue replacement implant system; such services being more specifically detailed in Attachment No. 1 to this Task Order which is incorporated herein by reference. The Scope of Work which is here stated covers the use of the TES system for use as a medical device for the indication of cartilage replacement for repair of cartilage defects in and around the knee, but exclusive of use within the synovial space.

At Histogenics Corporation's request additional Task Orders may be written in future to cover other tissue indications for the TES system (i.e., non-cartilage) and/or this Task Order may be amended to include additional specific indications for the TES system as a cartilage replacement for damaged cartilage at sites other than the knee. It is anticipated within the Scope of Work in this present Task Order, however, that the GMP qualification of the TES system's hardware and software which are used for preparatory culture and growth of the replacement tissue implant itself will be generally useful to support both Histogenics Corporation's and other parties future applications for approval of the TES system in such other indications.

COSTS:

SRS will conduct the Scope of Work for the following costs:

Base Program:

As specified in the program cost proposal submitted to Histogenics Corporation and dated November 16, 2000 and as amended per discussions between Histogenics Corporation and SRS International Corporation the Base Program cost for the above stated Scope of Work (exclusive of travel) is estimated as:

Through Phase I Clinical Study

SRS International fees for Base Program	$ 177,273.50
Non-clinical Laboratory fees for Base Program	$ 57,000.00
Clinical Site fees for Base Program	$ 129,500.00
Base Program Subtotal 1	$ 363,773.50

From Phase II/III Clinical Study and through PMA Approval

SRS International fees for Base Program	$ 594,552.13
Non-clinical Laboratory fees for Base Program	$ 0.00
Clinical Site fees for Base Program	$1,500,000.00
Base Program Subtotal 2	$2,094,552.13

Complete Program From Start-up through PMA Approval

SRS International fees for Base Program	$ 771,825.63
Non-clinical Laboratory fees for Base Program	$ 57,000.00
Clinical Site fees for Base Program	$1,500,000.00
Base Program Total ..... (Subtotal 1 + Subtotal 2)	$2,328,825.63

The details of the above-stated Base Program cost estimates are provided in Attachment No. 2 to this Task Order which is incorporated herein by reference. This cost estimate figure is provided as a good faith estimate based on: (a) SRS Internationals' experience with data requirements and approval issues for medical implant devices; (b) SRS International's preliminary cost discussions with various laboratory service vendors with whom SRS

International has experience; and, (c) SRS International's stated assumptions as to clinical trial design and experience with cost factors for such clinical trials. Both Histogenics Corporation and SRS International Corporation agree that: (1) SRS International will use its best efforts to provide needed laboratory and clinical studies at the lowest bid price from vendors which is consistent with quality and timeliness of performance; (2) that SRS International will not let any non-clinical or clinical study without Histogenics Corporation being first provided for its own review with the bids obtained by SRS International Corporation and Histogenics Corporation's approval of SRS International's selection of appropriate non-clinical and clinical study sites; (3) that as may be required by FDA requests or by changes in the study design assumptions set forth herein that the associated costs for non-clinical laboratory studies, clinical studies, and certain portions of SRS International's fees associated with the management, monitoring, evaluation, and reporting of same may change; provided however, that no change order to the costs above estimated shall be made without Histogenics Corporations' prior review and approval, which approval shall not unreasonably be withheld unless Histogenics Corporation decides as a result to revoke this Task Order pursuant to the revocation provision of the Master Consulting Agreement.

Contingent Program if Device Persists 28-Days or Greater:

As specified in the program cost proposal submitted to Histogenics Corporation and dated November 16, 2000 and as amended per discussions between Histogenics Corporation and SRS International Corporation the Contingent Program cost for the above stated Scope of Work (exclusive of travel) is estimated as:

Contingent Studies to be Completed Prior to IDE, Only if Required

SRS International fees for Contingent Program	$ 31,500.00
Non-clinical Laboratory fees for Base Program	$ 210,000.00
Clinical Site fees for Base Program	$ 0.00
Contingent Program Total 1	$ 241,500.00

The details of the above-stated Contingent Program cost estimates are provided in Attachment No. 2 to this Task Order which is incorporated herein by reference. This cost estimate figure is provided as a good faith estimate based on: (a) SRS Internationals' experience with data requirements and approval issues for medical implant devices; and, (b) SRS International's preliminary cost discussions with various laboratory service vendors with whom SRS International has experience. There are no clinical studies or costs associated with the above-stated Contingent Program. This Contingent Program is expected to be triggered only in the event that the TES tissue implant persists at the site of implantation greater than or equal to 28-days post-implantation (in which case it is typically considered to be a permanent implant by FDA). Both Histogenics Corporation and SRS International Corporation agree that: (1) SRS International will use its best efforts to